

Message Text

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15

ORIGIN HEW-08

INFO OCT-01 EA-11 ADP-00 SCI-06 EB-11 RSC-01 /038 R

DRAFTED BY DHEW/FDA:WJKUSTKA:DJ (RETYPE 7/13/73)

7/13/73 EXT 34480

APPROVED BY SCI:MSBEAUBIEN

SCI/SA:RYODER (INFO)

EA/ANP:MR. DORRANCE (PHONE)

DHEW/OIH:MACODDING

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R 132158Z JUL 73

FM SECSTATE WASHDC

TO AMEMBASSY CANBERRA

UNCLAS STATE 137970

E.O. 11652: N/A

TAGS: TPHY, TBIO, AS

SUBJ: PHARMACEUTICALS: HEALTH DEPARTMENT QUERY ON DEPO-
PROVERA

REF: CANBERRA 3277, CANBERRA 3649

FOOD AND DRUG ADMINISTRATION (FDA) ADVISES THAT A RECOM-
MENDATION HAS BEEN MADE BY FDA'S OBSTETRICS AND GYNECOLOGY
ADVISORY COMMITTEE THAT DEPO-PROVERA BE APPROVED FOR
CONTRACEPTION IN A RESTRICTED POPULATION, BASED ON ALL
AVAILABLE DATA (PRECLINICAL AND CLINICAL) RELATIVE TO
PRODUCT'S SAFETY AND EFFICACY.

DECISION TO APPROVE PRODUCT FOR CONTRACEPTION IS BASED ON
FACT THAT DEPO-PROVERA IS UNIQUE IN THAT IT IS AN INJECT-
ABLE GIVEN ONCE EVERY THREE MONTHS AND IS SUITABLE FOR A
SMALL SEGMENT OF THE POPULATION OF U.S. WOMEN NEEDING
CONTRACEPTION PROTECTION.

PRODUCT HAS NOT YET BEEN APPROVED FOR MARKETING SINCE
PROBLEMS OF LABELING AS WELL AS LIMITATION OF DISTRIBUTION
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AND MONITORING PATIENT USAGE MUST BE RESOLVED. WE CANNOT

SUPPLY APPROVED LABELING SINCE THIS IS STILL THE SUBJECT
TO BE RESOLVED.

DEPO-PROVERA HAS BEEN APPROVED IN U.S. FOR USE IN TREAT-
MENT OF INOPERABLE ENDOMETRIAL METASTATIC CARCINOMA.

FDA REQUESTS THE AUSTRALIAN DEPARTMENT OF HEALTH CONFINE
USE OF ABOVE INFORMATION TO OFFICIAL PERSONNEL ONLY.
QUESTION OF WHETHER AN NDA IS TO BE APPROVED IS NOT PUBLIC
INFORMATION UNTIL AFTER THE FACT. RUSH

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Disposition Approved on Date:
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Disposition Event:
Disposition History: n/a
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